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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,974	06/20/2001	Mark Laurence Brader	X-11869	9992

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,974	BRADER ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

Claims 1, 9 and the dependent claims hereto are indefinite because the claim recites the acronym "GLP-1" without the spelled out meaning which is insufficient to convey what applicant intends to be the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4, 6-10, 14-18, 22-23 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Jensen et al. (WO 96/20005, July 15, 1996).

Jensen et al. teach a composition containing glucagon-like-peptide-1 (GLP-1), a pharmaceutically acceptable preservative, a tonicity modifier that is glycerol (claims 1 and 9 of the instant application, pages 1-2, 7 and 10 of the reference), compounds having protracted action (claim 25) and a process for preparation thereof (pages 1-2 of the reference). Jensen et al. teaches a composition having a pH of 8.7 that falls within the range of pH recited in claims 1 and 9 (page 8 of the reference). The composition taught by Jensen et al. consists of a pH buffering agent (claims 2, 10 and 18 of the instant application, page 4 of the reference). Jensen et al. also teach that the protracted compositions will spare the diabetics the chore and discomfort of multiple daily injections (claim 25, see page 1-2). Jensen et al. further teaches GLP-1 compounds and polypeptides comprising 7-34 amino acid sequences of GLP-1, for example, formula I: His-Ala-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gln-Ala-Ala-Lys-Glu-Phe-Ile-Ala-Trp-Leu-Val-Lys, the sequence reported in the instant application as SEQ ID NO: 3 (claims 8, 6, 7, 15,16 and 23-24, page 3). Jensen et al. discloses a sequence with substantial sequence identity to the sequence contained in SEQ ID NO: 2 (claims 6, 7, 14-15 and 22-23, page 3). Jensen et al. also teach the above peptide and derivatives of this peptide without eliminating the GLP-1-like activity (claim 8, page 3). Therefore, the limitations of the claimed invention are met by this reference.

3. Claims 1-2, 6-10, 14, 16-18, 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Andrews et al. (WO 93/25579, December 23, 1993).

Andrews et al. teach a composition containing glucagon-like-peptide-1 (GLP-1), salts and derivatives of the claimed protein (claims 1 and 9 of the instant application, pages 1-2 of the reference). Andrews et al. teach the sequences set forth in claims 6-8 and 14-16 with a 100% sequence identity to SEQ ID NOS: 2 -3. The composition taught by Andrews et al. consists of a pH buffering agent (claims 2, 6, 7, 10, 14, 18 and 22 of the instant application, pages 1 and 10 of the reference). Andrews et al. also teach the above peptide and derivatives of this peptide without eliminating the GLP-1-like activity and a method of enhancing insulin action (claim 8, page 21). Although, Andrews et al. do not teach the pH range recited in the claims, as the structure of the claimed peptide is the same, the pH is considered to be an inherent property. Therefore, the limitations of the claimed invention are met by this reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (U.S. Patent No. 5,908,830, October 30, 1997) in view of Jensen et al. (WO 96/20005, July 15, 1996).

Smith et al. discloses the use of TRIS (claims 3, 11 and 19) buffer at pH 8 in a combination therapy for the treatment of diabetes using for example, glucagon agonists (see abstract and columns 6 and 16). Additionally, Smith teaches a method to treat obesity and a feeding behavior modifying agent (see column 1), thus the method as recited in claim 26 of the instant application is obtainable as Smith teaches methods to treat obesity and diabetes. However, Smith et al. does not teach a GLP-1 analog.

Jensen et al. teach a composition containing glucagon-like-peptide-1 (GLP-1), a pharmaceutically acceptable preservative, a tonicity modifier that is glycerol (claims 1 and 9 of the instant application, pages 1-2, 7 and 10 of the reference), compounds having protracted action (claim 25) and a process for preparation thereof (pages 1-2 of the reference). Jensen et al. teaches a composition having a pH of 8.7 that falls within the range of pH recited in claims 1 and 9 (page 8, Example 4 of the reference). The composition taught by Jensen et al. consists of a pH buffering agent (claims 2, 10 and

18 of the instant application, page 4 of the reference). Jensen et al. also teach that the protracted compositions will spare the diabetics the chore and discomfort of multiple daily injections (see page 1-2). Jensen et al. further teaches GLP-1 compounds and polypeptides comprising 7-34 amino acid sequences of GLP-1, for example, formula I: His-Ala-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gln-Ala-Ala-Lys-Glu-Phe-Ile-Ala-Trp-Leu-Val-Lys, the sequence reported in the instant application as SEQ ID NO: 3 (claims 8, 6, 7, 15-16 and 23-24, page 3). Jensen et al. discloses a sequence with substantial sequence identity to the sequence contained in SEQ ID NO: 2 (claims 6, 7, 14-15 and 22-23, page 3). Jensen et al. also teach the above peptide and derivatives of this peptide without eliminating the GLP-1-like activity (claim 8, page 3). Jensen et al. disclose a composition comprising water, a pH buffering agent, an osmotic pressure controlling agent or other ancillary agents (page 4), thus a surfactant such as Brij 35 could be considered as one such ancillary agent as it is well known in the art that this prevents turbidity and surfactants are buffer additives (claims 4, 5, 12, 13, 20 and 21). Moreover, Brij 35 is known in the art as a very good nonionic surfactant.

Therefore, it would have been obvious to one of skill in the art to arrive at the claimed invention as a whole because Jensen et al. teach a composition containing glucagon-like-peptide-1 (GLP-1), a pharmaceutically acceptable preservative, a tonicity modifier, compounds having protracted action and a process for preparation thereof for the treatment of diabetes. Additionally, Smith et al. provides a composition aimed at treating diabetes and obesity. One of skill in the art would be motivated to combine the

teachings of the references as both references aim to treat diabetes utilizing glucagons and Jensen et al. teach that there is a need to provide a composition that will spare the diabetics the chore and discomfort to multiple daily injections. Thus, the claimed invention as a whole is prima facie obvious.

Conclusion

6. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

Christopher S. Low

CHRISTOPHER S. FLOW
SUPERVISORY PATENT EXAMINER
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